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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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07/10/2003

Daniel M. Lafontaine

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EXAMINER

YABUT, DIANE D

ART UNIT

PAPER NUMBER

3734

DATE MAILED: 07/24/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/616,622	Applicant(s) LAFONTAINE, DANIEL M.	
	Examiner Diane Yabut	Art Unit 3734	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 July 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-39 is/are pending in the application.
- 4a) Of the above claim(s) 11, 12 and 14 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10, 13 and 15-39 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 20 November 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>1/18/05; 10/25/04</u> . | 6) <input checked="" type="checkbox"/> Other: <u>IDS: 9/15/04</u> . |

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121.

This application contains claims directed to the following patentably distinct species of the claimed invention. The species are as follows:

<u>Species</u>	<u>Figure(s)</u>
1	2-6, and 10
2	7A
3	7B
4	8-9

Generic claim is Claim 1.

2. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.
3. Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.
4. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations

Art Unit: 3734

of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species.

MPEP § 809.02(a).

5. Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

6. The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

7. Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Art Unit: 3734

8. During a telephone conversation with Thomas Miller on Tuesday, July 11, 2006 a provisional election was made without traverse to prosecute the invention of Species 1 directed towards Figures 2-6 and 10 and Claims 1-10,13, and 17-39. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

9. Affirmation of this election must be made by applicant in replying to this Office action. Claims 11,12, and 14 which read on Species 2-4, are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to non-elected inventions.

Information Disclosure Statement

10. The information disclosure statement (IDS) submitted on 15 September 2004 is acknowledged. In addition, the IDS submitted on 25 October 2004 and the IDS submitted on 18 January 2005 are also acknowledged. The submissions are in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statements are being considered by the examiner.

Specification

11. The disclosure is objected to because of the following informalities: On page 6, line 15 it reads "cone shaped" and should be changed to --cone-shaped--. On page 7, line 27 it reads "there uncompressed" and should rather read --their uncompressed--. On page 14, line 11 it reads "arrows 90" and should be changed to --arrows 94--. Appropriate correction is required.

12. The use of the trademark Velcro has been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Claim Rejections - 35 USC § 102

13. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

14. Claims 1-7, 13, and 24-39 are rejected under 35 U.S.C. 102(b) as being anticipated by **Lafontaine et al.** (U.S. Patent No. **5,964,782**).

Claims 1, 33, and 34: Lafontaine et al. discloses a closure device comprising an elongate delivery member **334** having a distal end and a proximal end and a closure component **344** removably connected to the distal end of the delivery member, the

Art Unit: 3734

closure component including a collapsible backing, movable between a non-collapsed position and a collapsed position, and a plurality of fibrous tissue engaging members disposed on the backing and oriented in a non-engaging orientation when traveling in a distal direction and in an engaging orientation when traveling in a proximal direction, the fibrous tissue engaging members entangling the backing when the backing is in the collapsed position (Figure 34A and col. 17, lines 39-51).

Claims 2,3, and 35: Lafontaine et al. discloses a backing formed in a generally elongate conformation, along a generally longitudinal axis of the backing, in the non-collapsed position, and the backing collapsed generally along the longitudinal axis when in the collapsed position (Figures 35 and 37B).

Claims 4,5,36 and 37: Lafontaine et al. discloses the fibrous tissue engaging members forming proximally facing hooks that are spaced along the backing from a proximal portion thereof to a distal portion thereof when the backing is in the non-collapsed position (Figure 35).

Claims 6 and 38: Lafontaine et al. discloses the hooks entangle in the backing located proximal of the hooks as the backing moves from the non-collapsed position to the collapsed position (col. 17, lines 38-43 and col. 18, lines 24-29).

Claims 7 and 39: Lafontaine et al. discloses the body cavity **332** is defined by generally smooth tissue and has fibrous tissue proximal thereof and wherein at least a subset of the plurality of hooks **4** are oriented to engage the fibrous tissue as the hooks travel in a proximal direction relative to the fibrous tissue (Figures 34A-34C and col. 17, lines 27-42).

Art Unit: 3734

Claim 13: Lafontaine et al. discloses an active actuator **388** having a distal engaging end disconnectably connecting the closure component to the delivery member and a proximal end receiving an actuation input and actuating the distal engaging end to release the closure component in response to the actuation input (col. 20, lines 14-19).

Claims 24 and 25: Lafontaine et al. discloses the closure component is formed of a biocompatible, bioabsorbable material (col. 4, lines 62-67).

Claim 26: Lafontaine et al. discloses a method of closing an opening **332** in a body comprising inserting distally through the opening a closure component **344** having collapsible pile backing with pile engaging hooks and tissue engaging hooks disposed thereon, withdrawing the closure component **344** proximally relative to the opening such that the tissue engaging hooks engage tissue adjacent the opening, and collapsing the collapsible pile backing so the pile engaging hooks engage portions of the pile backing (col. 17, lines 22-50).

Claim 27: Lafontaine et al. discloses inserting the closure component **344** with an elongate delivery member **334**, the closure component **344** being disposed at a distal end of the delivery member **334** (col. 17, lines 31-38).

Claim 28: Lafontaine et al. discloses disconnecting the closure component **344** from the distal end of the delivery member **334** (col. 18, lines 30-35).

Claim 29: Lafontaine et al. discloses exerting proximally directed force on the delivery member **334** after collapsing the collapsible pile (col. 18, lines 2-12).

Claim 30: Lafontaine et al. discloses moving a distal end of the closure component **344** toward a proximal end thereof (col. 17, lines 40-45).

Art Unit: 3734

Claim 31: Lafontaine et al. discloses the tissue engaging hooks being comprised of tissue piercing hooks that pierce the tissue when the tissue is engaged (col. 17, lines 38-40).

Claim 32: Lafontaine et al. discloses the opening **332** is in a body cavity defined by media and having adventitia adjacent thereto and wherein withdrawing comprises withdrawing the tissue engaging hooks proximally past the media to engage the adventitia (Figures 34A-34C and col. 17, lines 27-42).

Claim Rejections - 35 USC § 103

15. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

16. Claims 8-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Lafontaine et al.** (U.S. Patent No. **5,964,782**) in view of **Herrick** (U.S. Patent No. **5,723,005**).

Claims 8-10: Lafontaine et al. discloses the claimed device, including a closure component having a first row of hooks disposed about a proximal end thereof including tissue piercing hooks that pierce tissue and pass along the generally smooth tissue without engaging the generally smooth tissue and engage the fibrous tissue as the closure component is moved proximally relative thereto (Figure 34A-34C and col. 19, lines 54-67), except for the closure component being generally conical.

Herrick teaches a closure component being generally conical and is collapsible (col. 8, lines 63-67 and col. 4, lines 38-41). It would have been obvious to one of ordinary skill in the art at the time of invention to provide a closure component in a conical shape, as taught by Herrick, to Lafontaine et al. in order to provide a conical shape allows for a device to be collapsed, or flattened into a disk shape.

17. Claims 15 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Lafontaine et al.** (U.S. Patent No. **5,964,782**) in view of **Urbanski** (U.S. Patent No. **6,261,309**).

Claim 15: Lafontaine et al. discloses the claimed device except for a collapse actuator when actuated moves the closure component from the non-collapsed position to the collapsed position.

Urbanski teaches a hemostatic plug with a collapse actuator **90** when actuated moves the closure component **11** from the non-collapsed position to the collapsed position (col. 4, lines 44-51). Urbanski teaches that the application of a threshold axial force allows for the plug to collapse, which minimizes the chance of arterial penetration and applies continuous pressure on the puncture site necessary for a quick effective closure of the wound (col. 2, lines 62-67 and col. 3, lines 1-3). It would have been obvious to one of ordinary skill in the art to provide a collapse actuator, as taught by Urbanski, to Lafontaine et al. in order to minimize the chance of arterial penetration and effective closure of the wound.

Claim 16: Lafontaine et al. discloses an elongate member **334** having a distal end disconnectably connected to a distal end of the closure component **344**, the elongate

member **334** being configured to move the distal end of the closure component **344** to a more proximal position to collapse the closure component **344** under proximally directed force applied to the elongate member **334** (Figures 34A-34C and col. 17, lines 31-43).

18. Claims 17-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Lafontaine et al.** (U.S. Patent No. **5,964,782**) and **Urbanski** (U.S. Patent No. **6,261,309**), as applied to Claim 16 above, and further in view of **Redmond et al.** (U.S. Patent No. **6,334,865**).

Claims 17-20: Lafontaine et al. and Urbanski disclose the claimed device, including the elongate member being received within a distal aperture in the closure component (Figure 34A), except for a deformable hook at the distal end of the elongate member, the deformable hook being located distal of the distal aperture when the closure component is in the non-collapsed position, the deformable hook moving a distal end of the closure component to a more proximal position to collapse the closure component under proximally directed force applied to the elongate member, and the deformable hook deforming to pass through the distal aperture in the closure component.

Redmond et al. teaches a deformable hook **22** at the distal end of an elongate member **20** that grasps a closure component **26** and moves a distal end of the closure component to a more proximal position to collapse the closure component under proximally directed force applied to the elongate member and wherein the deformable hook is located distal of the distal aperture in the closure component **22** when the closure component is in the non-collapsed form, the deformable hook **22** capable of

Art Unit: 3734

deforming to pass through the distal aperture in the closure component **22** after the closure component **22** has moved to the collapsed position under continued application of proximally directed force on the elongate member **20** (Figures 1-4, col. 26-37). It would have been obvious to one of ordinary skill in the art to provide a deformable hook at the distal end of the elongate member, as taught by Redmond et al., to Lafontaine et al. and Urbanski, since it was known in the art that a deformable hooks are useful in manipulating devices in blood vessels and moving through the distal ends of elongate members.

Claim 21: Lafontaine et al. discloses the elongate member **334** comprising a wire (Figure 34A).

Claims 22-23: Lafontaine et al. discloses the wire **334** comprising a frangible, mechanically releasable connection to the distal end of the closure component (col. 20, lines 14-19).

Conclusion

19. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. **Conston et al.** (U.S. Patent No. **5,456,693**) discloses a conical embolization plug; **Girton** (U.S. Patent No. **6,537,300**) discloses a collapsible, conical obstruction device for septal defects.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Diane Yabut whose telephone number is (571) 272-6831. The examiner can normally be reached on M-F: 9AM-4PM EST.

Art Unit: 3734

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hayes can be reached on (571) 272-4959. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

DY



MICHAEL J. HAYES
SUPERVISORY PATENT EXAMINER